Remarks

Upon entry of the present amendment, claims 41-58 will be pending in the application, with claims 41 and 58 being the independent claims. Claims 59-66 have been canceled without disclaimer, and without prejudice to subject matter encompassed within one or more of the claims being presented in an application claiming the benefit of priority of the subject application. Support for the amendment to claims 41 and 58 may be found in the specification at page 4, lines 9-12. No new matter is added by way of these amendments, and their entry is respectfully requested.

Applicants respectfully request that the Examiner consider the above amendments and the following remarks, and withdraw the outstanding rejections.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 41-58 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is traversed. In particular, Applicants' specification is characterized as lacking written description for claims directed to expression vectors having a Kozak sequence linked upstream of any open reading frame (ORF), including ORFs derived from "any bacteria, any fungus, any vertebrate, and any invertebrate" (see Office Action at page 3). Applicants respectfully disagree with this characterization.

The claims recite expression vectors that include the sequence 5'-CACC linked immediately 5' to a start codon of an open reading frame (ORF). The specification fully supports these claims.

With respect to ORFs, the specification teaches that well known public databases can be used to identify ORFs, including prokaryotic, fish, mammalian (*e.g.*, human and mouse), and plant ORFs, for use in the invention:

> "Public databases exist that contain the entire or partial genome of a particular organism, for example yeast (*Saccharomyces cerevisiae*), **prokaryotes** (*Bacillus subtilis*, *E. coli*, *Borrelia burgdorferi*, *Heliobacter pylori*, *Mycoplasma genitalium*, and the like), **fish** (*Fugu rubripes*), **mammals** (**human**, **mouse**), **plants** (rice, cotton) and the like. Well known databases include GenBank, Unigene, EMBL, IMAGE and TIGR, for example. Public databases such as these can be used a source of gene sequences for use in the method of the invention."

(Specification at page 3, line 27 to page 4, line 3; bold added)

The specification goes on to describe the linkage of Kozak sequences immediately 5' to a start codon of an ORF, using 5'-CACC primers to make inserts for expression vectors that enhance the translational efficiency of the cloned gene sequence:

> "The primers employed in the amplification step are specific for each desired gene sequence and include a variety of unique features. For example, the 5' "sense" primer starts with the sequence 5'-CACCATG... (the start codon is underlined). The CACC sequence is added as a Kozak consensus that aids in translational efficiency."

(Specification at page 4, lines 9-12). Thus, the linkage of 5'-CACC immediately 5' to a start codon of an ORF is described in the context of ORFs from any organism.

Applicants' specification provides substantial teaching regarding the construction of expression vectors that include the sequence 5'-CACC linked immediately 5' to a start codon of an

ORF. Example 1 of Applicants' specification teaches the use of 5'-CACC primers to make expression vectors containing Kozak-linked yeast ORFs. Example 2 of Applicants' specification teaches the use of "...specific primer sets, essentially as described above..." (*i.e.*, 5'-CACC primers as in Example 1) to make expression vectors containing Kozak-linked human ORFs.

Applicants need not provide an example of every species of a given genus to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. The Federal Circuit has instructed that what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). In addition, the Federal Circuit has instructed that a specification that teaches those of skill in the art to make and use an invention can be sufficient to show such artisans that the inventor possessed the invention. *See Moba, B.V. v. Diamond Automation, Inc.*, 325F. 3d 1306, 1321 (Fed. Cir. 2003) ("the specification that teaches one of skill in the art to make and use an invention also convinced that artisan that the inventor possessed the invention.").

Given the level of knowledge readily available in the art (as described in Applicants' Specification) and Applicants' "make and use" teachings, those skilled in the art would have understood Applicants to have been in possession of the claimed invention when the application was filed. In accord with *Hybritech* and *Moba*, Applicants' Specification clearly conveys to those skilled in the art that Applicants had possession of the claimed invention at the time of filing, and expression vectors having 5'-CACC linked to the start codon of *every ORF* need not be disclosed.

Thus, the specification is fully compliant with the written description requirement of 35 U.S.C. § 112, first paragraph, and Applicants therefore respectfully request that the rejection be reconsidered and withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Richard J. Imbra
Registration No. 37,643
Telephone: (858) 677-1496
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133
USPTO CUSTOMER NO. 28213